5-14-02

AF/1600 1 CASE 4-30096/A

5/20/02

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

Express Mail Label Number

May 13, 2002 Date of Deposit C. Styles

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1624

ilu Darahar

ZIMMERMANN ET AL.

Examiner: Emily Bernhardt

APPLICATION NO: 09/463,097

FILED: JANUARY 18, 2000

FOR: CRYSTAL MODIFICATION OF A N-PHENYL-2-PYRIMIDINEAMINE

DERIVATIVE, PROCESSES FOR ITS MANUFACTURE AND ITS

USE

Assistant Commissioner for Patents Washington, D.C. 20231

REPLY BRIEF

Sir:

In response to the Examiner's Answer dated March 12, 2002, response due by Monday, May 13, 2002, Appellants request entry and consideration of this Reply Brief.

## **Grouping of Claims**

Section (7) of the Examiner's Answer incorrectly indicates that the Appeal Brief does not contain a statement that the claims should be considered separately with regards to the 112 rejections. However, on page 3 of the Appeal Brief, in the first paragraph under the heading "(7) Grouping of Claims" the Appeal Brief indicates that each of the rejections under 35 USC 112 is argued separately and should be considered separately. Therefore, the claims do not stand or fall together for purposes of considering the rejections under 35 USC 112.

TECH CENTER 1600/29(

## Rejection of Claim 14 Under 35 USC 112, First Paragraph

The Examiner's Answer asserts that claim 14 is directed to a method of treating any and all types of tumors and is not enabled based solely on the assay testing reported in the specification. However, the assay testing reported in the specification teaches the skilled artisan that the inventive crystal form is an inhibitor of tyrosine kinases, the overexpression of which is associated with certain tumor conditions. From this disclosure, it is clear that the tumors to be treated are those that the skilled artisan would expect to respond to a tyrosine kinase inhibitor. The Examiner's Answer does not allege that it would require undue experimentation for the skilled artisan to diagnose such a tumor condition, and Appellants assert that there is sufficient guidance in the specification to enable one of ordinary skill in the art to select appropriate tumors for treatment and to treat such tumors with the inventive crystal form. Therefore, the enablement requirement is satisfied, and the rejection should be reversed.

Appellants further note that the caselaw cited in the Examiner's Amendment, <u>In re Buting</u>, 163 USPQ 689 (CCPA 1969) relates to a rejection under 35 USC 101 and not to a rejection under 35 USC 112.

## Conclusion

Entry of this Reply Brief is requested.

Respectfully submitted,

Novartis Corporation Patent and Trademark Dept. 564 Morris Avenue Summit, NJ 07901-1027 (908) 522-6922

Date: May 13, 2002

George R. Dohmann Attorney for Applicants Reg. No. 33,593